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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,146	11/17/2000	Christopher T. Boyle	6006-018	6734

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ROSENBAUM& ASSOCIATES,P.C.
650 DUNDEE ROAD
SUITE 380
NORTHBROOK, IL 60062

EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/716,146	BOYLE, CHRISTOPHER T.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,20,26-28 and 30-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16, 20, 26-28, and 30-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/11/06, 10/05/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Attachments 1-5*.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 3008 has been entered.

Information Disclosure Statement

Previously crossed out IDS filed September 11, 2006 has been considered by the examiner and attached hereto. IDS filed October 5, 2007 has also been considered and attached hereto.

Response to Arguments

Applicant's arguments with respect to claims 16, 20, and 26-28 have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendment has overcome the Yan (US 5,843,172) rejection.

Board Decision

The board decision mailed April 30, 2008 reversed the rejection of Brown (US 6,071,305), agreeing with the applicant that the claims require *both* the base layer and second layer of the structural elements to be made of metal, thus reversing the rejection of Brown since the examiner had interpreted the structural elements to only *comprise* metal, and not necessarily

both layer requiring the metal (the examiner had interpreted membrane and osmotic material to constitute a "layer", however these "layers" were not metal; in figures 5, 7, 8, and 10 of Brown shown in attachments to examiners answer). The board reversed Brown due to the interpreted "layers" of the examiner were not each metal, as required by the claim. This is relevant since Brown has been applied herein *under a different interpretation* in which a different embodiment contains both a base and second layer each being metal, see below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 20, 26-28, and 30-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1) Claim 16 recites, "having microstructural properties *characteristic of a vacuum deposited metal*". It is noted that this is a product by process limitation and covers a structure having a particular microstructural property, however does not require a vacuum deposition process (See MPEP 2116-consideration given to end product not method of manufacture). Therefore, applicant is attempting to claim broader coverage than applicant has support for since such microstructural properties may be manufactured by a different means, however applicant

ONLY has support for forming certain properties ***by*** vacuum deposition not properties *characteristic* of vacuum deposition however possibly made from a different process.

2) Applicant further does not have support for "having *microstructural properties characteristic* of a vacuum deposited metal". Although the incorporated by reference application 09/443,929 discusses controlling heterogeneities, there is no reference to microstructural properties in particular (which may be different or broader in scope than heterogeneities). Microstructural properties in unclear and indefinite. What microstructural properties is applicant referring to? No microstructural properties has been defined, and it is impossible to tell whether material disclosed in prior art have such "microstructural properties" when it is unclear what applicant is even referring to. It is not clear what applicant is referring to and further there was not support found for the term "microstructural properties" in the specification or the specification of the referenced incorporated by reference application.

3) Applicant does not have support for a void space "completely enclosed" between the layers. As the plurality of pores present openings in the layers, such void space cannot be **completely** enclosed. The amendment reciting the void space only open through the pores is acceptable, however complete enclosure is considered new matter, as both may not be present at the same time, when the pores are present, the void space is not and cannot be **completely** enclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 20, 26-28, and 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 6,071,305, cited previously) in view of Whicher et al. (US 6,938,668 B2). Brown discloses an endoluminal stent for delivering a bioactive agent (col.1, lines 12-20) comprising a plurality of structural elements (12; only one structural elements is shown in fig.1, 2 however a plurality of structural elements 12 are disclosed as additional possible embodiments at col.7, lines 34-39; mesh stent, each filament of the plurality of filaments in the mesh being a member 12), each structural element (12) having a wall thickness (cross sectional thickness of an element 12 seen in figs.3-10) and fabricated of metal (col.7, lines 11-18) comprising a base layer (considered luminal surface or layer 18) and a second layer (considered abluminal surface or layer 19) covering the base layer (see figures 2A, 3, 6, 8 and attachments 2-5 which more clearly show location of "layers"), a void space (20) intermediate the layers, a plurality of pores (22, 28, 54) passing through the second layer (19), such that the void space is only open through the pores (see figs.3, 6 for example), and at least one bioactive agent (23; col.5, lines 1-27).

*with respect to the term “layer”: applicant's only recitation of the word layer is referral to a deposition process, in which layer upon layer is deposited until forming one unitary device (seen in applicant’s figures). The claims refer to a stent which is shown in applicants figures 2-7, which contains structural elements 21 or 31 shown generally cylindrical, having a longitudinal axis (shown in figure 7) and a round cross-section (shown in fig.3 and 6-figure 6 shown two adjacent structural elements). The “layers" are not clearly pointed out in the figures as the specification only refers to "layers” as depositing layer upon layer to form the device shown in

the figures. It is not clear where one layer starts and ends, but it would appear applicant is referring to an abluminal and luminal "layer" (referenced as 26, 28, 33, 35). Brown has shown the same type of structural elements 12, having a generally round cross-section (figs.3-10) with an inner void space 20. Structurally, the elements of Brown are the same as the applicants (compare fig.2a of Brown to fig.7 of applicant; compare fig.3, 6, 8 of Brown to applicants fig.6-keep in mind that applicants fig.6 shows two side by side structural elements; see attachments 1-5). The structural elements are the same. Therefore, a "layer" of applicant's structural element may also be considered a "layer" of Brown's structural element. See attachments, wherein the second layer is shown shaded to distinguish it from the base layer, both layers being part of structural element 12 which is fully made of metal, both layers are metal.

Brown discloses an endoluminal stent substantially as claimed (see above), however does not disclose a metal having microstructural properties characteristic of a vacuum deposition process. Brown is silent to mention any method of manufacture for stent 11 (only method disclosed is for embodiment in fig.17, method shown in figs.13-18; col.11, lines 62-67; which is disclosed as cutting by laser or other conventional cutting means). Whicher teaches in the same field of endoluminal stents, a method of making a stent by using vacuum deposition techniques (col.3 line 52-col.4 line 30) as an improvement over older techniques such as cutting and etching etc. (col.1, lines 31-51; cutting being the only type mentioned by Brown), in order to improve the properties of the material (discloses control of microstructure, col.2, lines 6-9; col.3, lines 18-25; also as Whicher discloses the same method of manufacture, vacuum deposition, Whicher process will inherently produce microstructure and heterogeneities characteristic of such a process). It would have been obvious to one having ordinary skill in the art at the time the invention was

made to combine Brown's endoluminal stent shape, with Whicher's method of manufacture (vacuum deposition) in order to provide a stent with improved material properties (characteristic of such a process)

Referring to dependent claims, Brown discloses a degradable plug (biodegradable matrix 27; shown in the cavities and extending into the pores, see fig.3, 9 for example; col.8 line 62-col.9 line 5), the metals claimed (col.7, lines 12-18), bioactive agents claimed (col.5, lines 1-27), and a plurality of independent cavities (each structural element 12 in the mesh stent may have its own cavity, thus plurality of cavities amongst all the structural elements 12; further, elements 12 are shown to have multiple cavities fig.9 for example; further, at least one cavity is disclosed, encompassing more than one, col.2, lines 59-61). The claimed controlled heterogeneities are inherent to the deposition process taught by Whicher (As Whicher discloses the same process as the applicant and further discloses controlling the microstructure, such heterogeneities are inherently controlled just as much as they are "controlled" by the applicant).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738